

# InterGard silver bifurcated graft: Features and results of a multicenter clinical study

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**Objectives:** Recent research in vascular surgery has focused on development of infection-resistant prosthetic grafts. This article describes the results of a multicenter study to evaluate safety, patency, and infection rates after implantation of the InterGard Silver bifurcated polyester graft coated with collagen and silver.

**Methods:** Between October 2000 and February 2002, 289 consecutive patients were implanted with a collagen and silver acetate-coated polyester bifurcated graft at 16 French vascular surgery centers. Mean patient age was  $65.3 \pm 10.9$  years. The indication for prosthetic bypass was aortic aneurysm in 160 patients (55.4%) and symptomatic aortoiliac occlusive disease in 129 (44.6%). All but four patients received prophylactic antibiotic therapy. Patency was assessed at 30 days, 1 year, 2 years, and 3 years, primarily by duplex scan.

**Results:** Two patients (0.7%) died during the first 30 days. Median duration of hospitalization was 11 days. The Kaplan-Meier survival rate at 3 years was  $85.7\% \pm 4.1\%$ . Primary and secondary patency rates at 3 years were  $94.9\% \pm 2.6\%$  and  $97.5\% \pm 1.8\%$ . Thrombectomy was performed successfully in seven patients, and a major amputation was required in two patients with patent grafts. Postoperative complications, including 39 nosocomial infections, were observed in 107 patients (37.0%). Eleven patients presented with 12 wound infections that were classified Szilagyi grade I in eight cases, grade II in two cases, and grade III with graft infection in two cases (0.7%). Among the 149 patients undergoing aortofemoral bypass, eight (5.4%) presented with wound infection, including two graft infections (1.3%). Among the 140 patients undergoing aortoiliac bypass, only three patients (2.1%) presented wound infection and none with graft infection ( $P = .15$ ). Three (16.7%) of 18 patients who had undergone previous femoral revascularization and eight (3%) of 271 patients without previous femoral revascularization presented with wound infection. This difference was statistically significant ( $P = .03$ ), with a relative risk of 5.6 (95% confidence interval [CI], 1.6 to 19.5). Five (11.9%) of 42 diabetic patients and six (2.4%) of 247 nondiabetic patients presented with wound infection. This difference was also statistically significant ( $P = .01$ ), with a relative risk of 3.4 (95% CI, 1.7 to 6.9). Lymphorrhea or lymphocele developed in the groin of 25 patients (8.6%) with negative culture.

**Conclusion:** This multicenter prospective study shows that the InterGard Silver graft is safe with no side effects. The primary patency rate was excellent, and the graft infection rate was low, despite a high incidence of nosocomial infections. (J Vasc Surg 2006;44:339-46.)

Aortic graft infection is a rare but life-threatening complication, occurring in 1.5% to 6.0% of patients despite antibiotic prophylaxis.<sup>1-4</sup> It is associated with a mortality rate of 20% to 75% and limb loss of 20% to 75%, depending on the type and location of the bypass.<sup>1-4</sup> A prosthetic graft with a collagen and silver acetate coating has recently been proposed to reduce the risk of prosthetic graft infection. The antimicrobial properties of silver are well documented<sup>5-7</sup> and have been used to enhance the infection resistance of a number of medical devices.

Statistical demonstration of the efficacy of this strategy is difficult in the clinical setting owing to the low incidence of graft infection. Because of this difficulty, not even the commonly accepted studies on antibiotic prophylaxis in vascular surgery have reached statistical significance regard-

ing prevention of graft infection.<sup>1-4</sup> The purpose of this prospective study was to evaluate safety, patency, and infection rate of a bifurcated aortic polyester graft coated with collagen and silver in a large series of consecutive patients. We also present the features and mode of action of this novel graft and the results of the 3-year follow-up of these patients.

## MATERIAL AND METHODS

**Silver graft concept.** The InterGard Silver (InterVascular, La Ciotat, France) is the first CE-approved graft designed to reduce the risk of graft infections. Silver is located in the collagen layer of the graft (Fig 1, A) and in the fabric of the graft itself (Fig 1, B), providing a substantial release immediately after implantation followed by a sustained release for up to 30 days.

Unlike antibiotics, silver has not been reported to increase bacterial resistance<sup>11,12</sup> because of its mode of action. In its ionic ( $\text{Ag}^+$ ) state, silver acetate exhibits bactericidal effectiveness against all bacteria.<sup>8</sup> The antimicrobial action of silver ions depends on several mechanisms. Silver ions penetrate the bacterial cell wall and bind to the phospholipid layer of the cytoplasmic membrane (Fig 2, A). The ions cause the cell membrane to detach from the cell wall,

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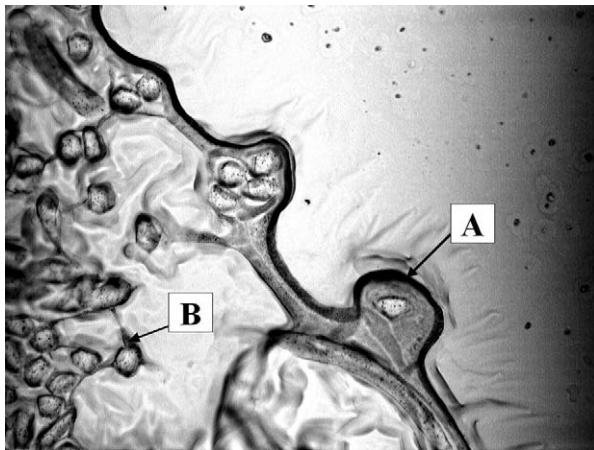
Competition of interest: Jean-Baptiste Ricco, MD, PhD, as main investigator of the study, has received fees for consulting from InterVascular, Inc.

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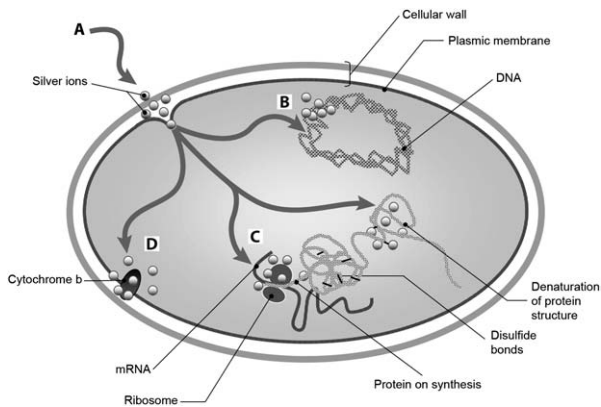
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**Fig 1.** Microscopic section of InterGard Silver graft ( $\times 220$ ) colored with Fast Green 1%. Silver distribution is seen both in collagen layer (A) and in graft fabric (B).



**Fig 2.** Mechanisms of action of the silver ions on bacteria. **A**, Silver ions penetrate the bacterial cell wall and bind to the phospholipid layer of the cytoplasmic membrane. The ions cause the cell membrane to detach from the cell wall, thus disrupting wall permeability and causing a gradual collapse of the first line of defense of the bacteria. **B**, Silver ions bind with the bacterial DNA, disrupting DNA replication and interfering with cell division. **C**, Silver ions impair the ability of ribosomes to transcribe mRNA, and prevent the protein from achieving a proper quaternary structure by binding to thiol groups in the proteins. **D**, Silver ions bind to the sulfhydryl group of the cytochrome b, shut down enzyme production, and eventually stop the cellular respiration.

thus disrupting wall permeability and causing a gradual collapse of the first line of defense of the bacteria.<sup>9,10</sup>

Another antimicrobial effect of silver ions consists of binding to transcribing DNA (Fig 2, B) at key locations along the helix.<sup>11</sup> This binding disrupts DNA replication and prevents further cell division.<sup>7,11,12</sup> Silver ions also act by impairing the ability of ribosomes to transcribe messenger RNA into the vital proteins required by the cell to function (Fig 2, C).

Thiol groups attract the positively charged silver ions,<sup>11-12</sup> resulting in the enzyme becoming denatured,

**Table I.** Arterial lesions treated in this series of 289 consecutive patients.

Lesions	Patients	Percentage
Aortoiliac occlusive disease	129	44.6
Aortoiliac aneurysm	129	44.6
AAA and iliac occlusive disease	31	10.8

AAA, Abdominal aortic aneurysm.

**Table II.** Main risk factors in this series of 289 patients treated for aortoiliac aneurysm or aortoiliac occlusive disease by implantation of bifurcated silver grafts

Risk factors	Patients*	Percentage
Systemic		
Smoking	224	77.5
Hypertension	165	57.1
Hyperlipidemia	147	50.9
Coronary artery disease	85	29.4
Cardiac insufficiency	12	4.2
Diabetes type I and II	42	14.5
Obesity	34	11.8
Renal insufficiency	22	7.6
Stroke	19	6.6
Local		
Previous aortic bypass	4	1.4

\*77 patients (26.6%) had only one risk factor, 88 patients (30.4%) had two risk factors, and 109 patients (37.7%) had three or more risk factors. Only 15 patients (5.2%) had no risk factor.

unraveling, and thereby losing its ability to function within the bacteria.<sup>11-13</sup> In another mechanism, silver ions hamper cellular respiration by halting adenosine triphosphate synthesis (Fig 2, D). Consequently, bacteria can no longer survive with both their structure and function under siege by the silver ions, and lysis occurs.<sup>11</sup>

**Clinical study.** From October 2000 to February 2002, the InterGard Silver bifurcated graft was implanted in 289 consecutive patients, 268 men (92.7%) and 21 women (7.3%), at 16 French vascular centers. Mean patient age was  $65.3 \pm 10.9$  years. Patients who required emergent treatment were excluded. The indication for treatment was abdominal aortic aneurysm (AAA) in 160 patients (55.4%), including 31 presenting associated iliac stenosis (Table I), and aortobiiliac occlusion or stenosis in 129 (44.6%). Symptoms included claudication in 134 (46.4%), critical ischemia in 35 (12.1%), and subacute ischemia in five (1.7%) patients. AAAs were asymptomatic in 103 patients.

For patients presenting with claudication, walking distance was  $<100$  meters in 81 (60.4%). In the 35 patients with critical ischemia, 25 (60%) had rest pain, and 14 (40.0%) had an ischemic ulcer or a gangrenous toe. Three of these patients were receiving preoperative antibiotics.

Risk factors are listed in Table II. In addition, 49 patients (17.0%) had undergone previous revascularization, including iliac stenting in 9, iliofemoral bypass in 5, aortic bypass in 4, and lower limb bypass in 8.

**Table III.** Location of distal anastomosis in this series of patients treated for aneurysmal or occlusive aortoiliac disease by implantation of 289 bifurcated silver grafts

Location of distal anastomosis	Anastomosis (N)	Percentage
Common or external iliac artery	284	49.1
Common femoral artery*	237	41.0
Deep femoral artery alone	51	8.8
Superficial femoral artery†	6	1.1

\*The graft limb to the common femoral artery (n = 237) was also anastomosed with a bifurcated graft to the deep femoral artery in 23 cases and to the superficial femoral artery in 31 cases.

†The graft limb was anastomosed both on the deep and superficial femoral arteries in four cases. In one patient, both graft limbs were anastomosed only on the superficial femoral artery.

**Surgical procedures.** All procedures were done under general anesthesia. Bypass was aortobifemoral in 143 cases (49.5%), aortobiiliac in 140 (48.4%), and bifurcated aortoiliacofemoral in 4 (1.4%). In the remaining two patients presenting with AAAs associated with iliac stenosis, the procedure consisted of bifurcated aortobifemoral grafting with sequential anastomosis to the internal iliac artery. All proximal aortic anastomoses were infrarenal with end-to-end configuration in 191 cases (66.1%) and end-to-side configuration in 98 (33.9%). Most distal anastomoses (Table III) were performed on the common or external iliac artery (n = 284) or common femoral artery (n = 237).

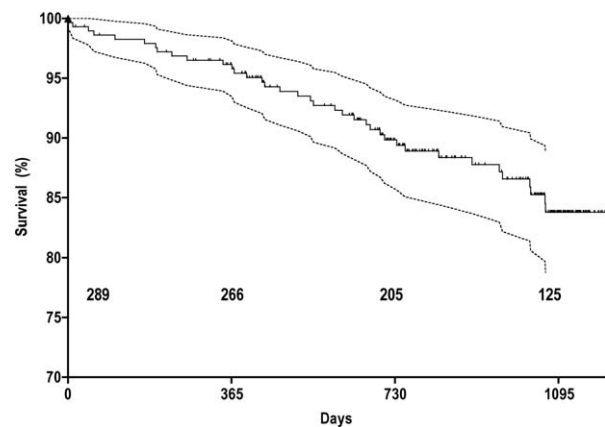
During the same procedure, 84 patients (29%) underwent associated vascular repair, including inferior mesenteric artery reimplantation in 33 cases, aortorenal bypass in 9, internal iliac revascularization in 12, peripheral angioplasty in 3, and femoropopliteal or tibial bypass in 9.

**Antibiotic and antithrombotic drugs.** Prophylactic antibiotic therapy was used in all but four patients (98.6%). Antibiotics used for prophylaxis were cefamandole in 96 patients (33.2%), cefazolin in 106 (36.7%), cefuroxime in 55 (19.0%), ciprofloxacin in 11 (3.8%), and a combination of several antibiotics in 16 (5.5%). Vancomycin was used in one patient with a suspected allergy to cephalosporins. At the time of discharge, 67 patients (23.2%) were still receiving some type of antibiotic therapy, mainly for respiratory and genitourinary tract infections.

Antithrombotic therapy was used in 273 patients (94.5%). The drugs used for antithrombotic therapy were anti-platelet agents in 213 patients (73.7%), antivitamin K in 22 (7.6%), and low molecular weight heparin in 78 (27.0%).

**Methodology.** Patients from each center were entered in consecutive order. Data were collected on a standardized case report form and entered on SPSS (SPSS France SA, Paris, France). All centers were regularly monitored to ensure data quality. The primary end point was graft patency. Secondary end points were patient survival and immediate and long-term complications.

Patency was assessed before discharge from the hospital, at 1 month after surgery, and yearly thereafter by duplex scan, computed tomography scan, magnetic resonance im-



**Fig 3.** Survival of patients enrolled in the study. Number of patients at risk is indicated. Survival at 1, 2, and 3 years was  $95.8\% \pm 2.3\%$ ,  $90.2\% \pm 3.5\%$ , and  $85.7\% \pm 4.1\%$  respectively. Dotted lines show 95 % confidence intervals.

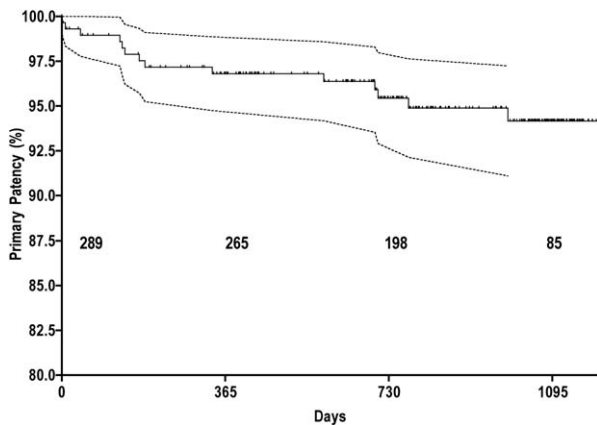
aging, or angiography. Complications were identified and defined in the protocol and case report form before the study was begun. All participating investigators agreed to follow the study protocol, and all complications were systematically reported. In addition, uniformity in complications reporting was verified during on-site monitoring visits by comparing complications recorded in source data with those in the case report form. To ensure full assessment of recognized graft-related problems, all postoperative complications were recorded, such as stenosis, dilatation, and anastomotic abnormalities. Wound infection was classified according to Szilagyi.<sup>14</sup> Graft patency and survival rates were calculated using the Kaplan-Meier method with 95 % confidence interval. Basic statistics were done using  $\chi^2$  analysis or Fisher exact test, when applicable. Survival data were compared using the log-rank test.

## RESULTS

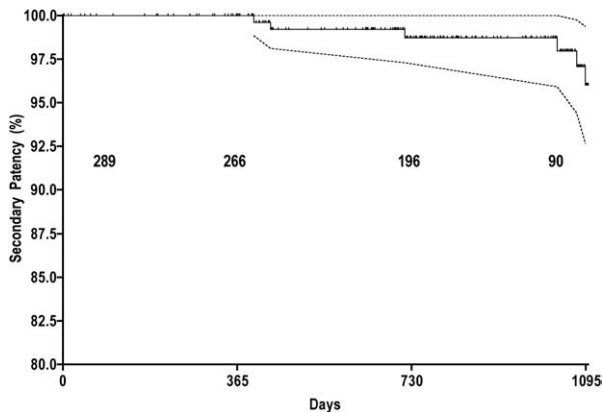
**Survival.** Two patients (0.7%) died during the first 30 days, one from colon and pelvic ischemia and one from cardiac and liver failure. Median hospital stay was 11 days. The mean length of follow-up for all patients was  $55 \pm 10$  months (25% percentile, 35 months; 75% percentile, 40 months). Eight patients (2.8%) were lost to follow-up. During follow-up, 45 patients (15.6%) died, mainly from cancer (n = 17) and complications of atheromatous disease unrelated to the graft (n = 16).

The cumulative survival rates at 1, 2, and 3 years were  $95.8 \pm 2.3\%$ ,  $90.2 \pm 3.5\%$ , and  $85.7 \pm 4.1\%$ , respectively (Fig 3). There was no difference in the survival of patients treated for occlusive vs aneurysmal disease ( $P = .41$ ).

**Patency.** One graft occlusion (0.35 %) involving only one limb occurred  $\leq 30$  days after surgery. Primary patency rates at 1, 2, and 3 years were  $96.8\% \pm 2.2\%$ ,  $95.7\% \pm 2.4\%$ , and  $94.9\% \pm 2.6\%$ , respectively (Fig 4). Fifteen graft occlusions occurred during follow-up. Seven were successfully treated by surgical thrombectomy, six required another



**Fig 4.** Primary patency of silver polyester bifurcated grafts. Number of patients at risk is indicated. Primary patency at 1, 2, and 3 years was  $96.8\% \pm 2.2\%$ ,  $95.7\% \pm 2.4\%$ , and  $94.9\% \pm 2.6\%$  respectively. The 95% confidence interval is shown on the figure.



**Fig 5.** Secondary patency of silver polyester bifurcated grafts. Number of patients at risk is indicated. Secondary patency was  $97.5\% \pm 1.8\%$  at 3 years. The 95% confidence interval is shown on the figure.

bypass, and two were not reoperated on. Twelve occlusions occurred in the 129 patients treated for occlusive disease compared with three in the 160 patients with aneurysmal disease. The difference between these two groups was statistically significant ( $P = .02$ ), with a relative risk of 0.53 (95% CI, 0.40 to 0.71). Overall patency in grafts with a limb diameter of  $\leq 7$  mm (88%) vs grafts with a limb diameter of  $\geq 8$  mm (96%), was not significantly lower ( $P = .08$ ), with a relative risk of 0.42 (95% CI, 0.19 to 0.90). Limb diameter was not reported in one patient with an occluded graft. Primary patency was not significantly lower in patients with risk factors including smoking and diabetes ( $P = .39$ ).

Secondary patency at 3 years was  $97.5\% \pm 1.8\%$  (Fig 5). Two of the seven patients who had been successfully treated for graft occlusion presented new occlusions that were again successfully treated by surgical thrombectomy. Major

**Table IV.** Postoperative complications occurring during the first 30 days in 107 patients (37%)

Complications	N
Surgical	50
Lymphorrhea/lymphocele from groin incision (not infected)	25
Infection (Szilagyi grade I or II)	9
Evisceration	6
Colon ischemia	5
Lower limb amputation with a patent aortobifemoral graft	2
Hematoma with drainage	2
Peripheral arterial embolism	1
General	18
Transient renal insufficiency (one patient requiring dialysis)	7
Deep venous thrombosis	6
Myocardial infarction, cardiac failure	5
Infection—nonvascular	39
Pulmonary infection	19
Urinary tract infection	17
Central line catheter with septicemia	3
Total	107

amputation was required despite graft patency in two patients with inoperable distal occlusive arterial disease.

**Intraoperative complications.** Intraoperative complications occurred in four patients. One patient underwent splenectomy during the procedure. Groin hematoma requiring immediate surgical hemostasis developed in two patients. One patient presented with thrombosis of both limbs of the graft immediately after clamp removal. Thrombosis was corrected successfully by surgical thrombectomy, and the graft remained patent during follow-up.

**Complications during follow-up.** Complications were observed during the first 30 days in 107 patients (37.0%) (Table IV). Postoperative pulmonary, urinary, and catheter-related infection occurred in 39 patients (13.5%). Eleven patients presented with postoperative wound infections. One patient who underwent aortofemoral bypass presented with superficial infection during the early postoperative period and deep infection at 2 years. There was no early postoperative graft infection.

According to the Szilagyi classification,<sup>14</sup> early postoperative wound infection was classified as grade I (superficial) in eight cases and grade II (deep) in one. Three late femoral infections occurred after surgery, including grade III aortobifemoral graft infections at 1 year in two cases, with one limb of the graft involved in both cases and grade II femoral infection at 2 years in one case.

Wound and graft infection according to the type of bypass or indication is presented in Table V. Although differences between groups did not reach statistical significance, a trend toward a higher incidence of wound infections was observed in the patients treated for occlusive disease ( $P = .06$ ).

Wound infection according to whether the patient underwent prior femoral surgery or presented diabetes is



**Table V.** Wound and graft infection according to type of bypass and indication

	According to type of bypass			P <sup>†</sup>
	Aortofemoral grafts*	Aortoiliac grafts*	All grafts*	
Grafts at risk	149	140	289	
Wound infection	8 (5.4; 1.8-9.0) <sup>‡</sup>	3 (2.1; 0-4.5)	11 (3.8; 1.6-6.0)	.15
Graft infection	2 (1.3; 0-3.2)	0	2 (0.7; 0-2.0)	0.5
	According to indications			
	Occlusive disease	Aortic aneurysm	All indications	
Grafts at risk	129	160	289	
Wound infections	8 (6.2; 2.0-10.4) <sup>‡</sup>	3 (1.9; 0-4.0)	11 (3.8; 1.6-6.0)	.06
Graft infections	2 (1.6; 0-3.5)	0	2 (0.7; 0-2.0)	0.2

\*Data in parenthesis are % and 95% confidence interval.

<sup>†</sup>Calculated by  $\chi^2$  test.

<sup>‡</sup>Including the two graft infections.

**Table VI.** Wound and graft infection according to whether the patient underwent previous femoral arterial surgery and the presence of diabetes

	Patients (n)	Infections (n)	Wound infection (%)	95% CI	P
<i>Wound infection according to prior femoral arterial surgery</i>					
No prior femoral surgery	271	8*	3.0	0.9-5.0	.03
Prior femoral surgery	18	3 <sup>†</sup>	16.7	0-33.9	
Total	289	11	3.8	1.6-6.0	
<i>Wound infection according to diabetes status</i>					
Diabetes	42	5*	11.9	2.1-21.7	0.01
No diabetes	247	6 <sup>†</sup>	2.4	0.5-4.3	
Total	289	11	3.8	1.6-6.0	

CI, Confidence interval.

\*Including one graft infection.

<sup>†</sup>Including one graft infection.

presented in Table VI. Wound infection (grades I, II and III) developed in three (16.7%) of 18 patients who had undergone previous femoral revascularization vs eight (3%) of 271 patients who had not undergone previous femoral revascularization. This difference was statistically significant ( $P = .03$ ), with a relative risk of 5.6 (95% CI, 1.6 to 19.5). Wound infection developed in five (11.9%) of 42 diabetic patients vs six (2.4%) of 247 nondiabetic patients. This difference was also statistically significant ( $P = .01$ ), with a relative risk of 3.4 (95% CI, 1.7 to 6.9).

Bacteriologic tests were performed for the 12 wound infections. Cultures were positive in all but two cases. In one case, no bacteria were found on direct examination, but *Staphylococcus epidermidis* was identified after culture. In the other nine cases, culture was positive for *S aureus* in four, including one that was methicillin-resistant, *S epidermidis* and *S aureus* in one case, and one case each of *Escherichia coli*, *Proteus mirabilis*, coagulase-negative *Staphylococcus*, and multiresistant *Serratia*.

The two patients with graft infection had reoperations. The procedure consisted of in situ replacement of the infected limb. The rest of the graft was left in place.

## DISCUSSION

This multicenter prospective study shows that the patency of the polyester bifurcated InterGard Silver graft with a collagen and silver acetate coating was comparable with that reported in other contemporary series describing aortofemoral or aortoiliac bypass.<sup>15,16</sup> Primary and secondary patency were not significantly altered by risk factors or patient age but only by underlying arterial disease. This series confirms previous results demonstrating better patency for patients treated for aneurysm than for occlusive disease ( $P = .02$ ).<sup>17</sup> No early graft infection occurred despite a high rate of nosocomial infections, and only two late graft infections (0.7%) occurred after 1 year.

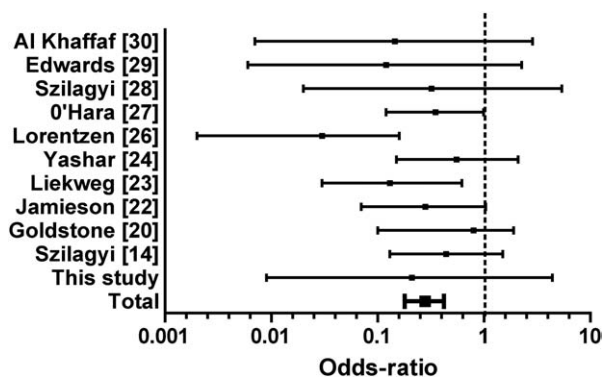
Our series, with a rate of graft infection of zero in the aortoiliac group and 1.3% in the aortofemoral group, compares favorably with previously published data. We were able to find 13 series<sup>14,18-31</sup> with a sufficient number of patients and adequate follow-up for each type of aortic bypass. Table VII lists series involving aortoiliac grafts and aortofemoral grafts. A meta-analysis of these series (Fig 6) confirmed that the risk of graft infection was significantly lower for aortoiliac than aortofemoral grafts, with an odds

**Table VII.** Graft infection in aortoiliac and aortofemoral grafts

Authors	Year	Study period	Patients	Graft infection (%)
In aortoiliac grafts*				
Szilagy <sup>14</sup>	1972	1952-1971	418	0.7
Goldstone <sup>20</sup>	1974	1959-1973	163	1.2
Bouhoutsos <sup>21</sup>	1974	1957-1972	412	0.5
Jamieson <sup>22</sup>	1975	1955-1973	325	0.9
Liekweg <sup>23</sup>	1977	1965-1974	265	0.7
Yashar <sup>24</sup>	1978	1966-1977	300	1.3
Crawford <sup>25</sup>	1981	1955-1980	860	0.7
Lorentzen <sup>26</sup>	1985	1978-1981	425	0
O'Hara <sup>27</sup>	1986	1959-1985	867	0.4
Szilagy <sup>28</sup>	1986	1954-1983	76	0
Edwards <sup>29</sup>	1987	1975-1986	769	0
Al Khaffaf <sup>30</sup>	1996	1989-1991	97	0
This series	2006	2000-2002	140	0
Graft infection in aortofemoral grafts†				
Szilagy <sup>14</sup>	1972	1952-1971	1244	1.6
Goldstone <sup>20</sup>	1974	1959-1973	260	3.0
Jamieson <sup>22</sup>	1975	1955-1973	315	3.1
Liekweg <sup>23</sup>	1977	1965-1974	123	5.6
Yashar <sup>24</sup>	1978	1966-1977	210	2.4
Lorentzen <sup>26</sup>	1985	1978-1981	1497	3.0
O'Hara <sup>27</sup>	1986	1959-1985	2785	1.3
Szilagy <sup>28</sup>	1986	1954-1983	1362	1.9
Edwards <sup>29</sup>	1987	1975-1986	1060	0.5
Al Khaffaf <sup>30</sup>	1996	1989-1991	102	2.9
Prager <sup>31</sup>	2003	1991-1998	149	4.0
This series	2006	2000-2002	149	1.3

\*Overall graft infection rate in these series was 0.5% (95% CI, 0.3-0.7).

†Overall graft infection rate in these series was 1.8% (95% CI, 1.5-2.1).



**Fig 6.** Plot comparing data concerning graft infection according to type of bypass, ie, aortofemoral or aortoiliac (Table VII), with calculation of odds ratio for each group. The meta-analysis demonstrates a combined odds ratio of 0.28 (95% confidence interval, 0.18 to 0.42), demonstrating that graft infection rate was significantly lower in aortoiliac grafts versus aortofemoral grafts. This confirms the tendency observed in our study (0.21 with 95% CI, 0.01 to 4.4).

ratio of 0.28 (95% CI, 0.18 to 0.42). This finding confirms the tendency observed in our study.

In our series, eight groin infections (5.4%), including two graft infections (1.3%), occurred in patients in whom graft limb anastomosis was made on femoral arteries. In addition, 25 patients (8.6%) presented with lymphocele or

lymphorrhea with no infection. There was no evidence in this study to suggest that the silver ions impair wound healing. Although they have been under-reported in the literature, postoperative groin wound problems are quite common after aortofemoral bypass. In a recent case control study on vascular graft infection from the Mayo Clinic,<sup>32</sup> the rate of groin wound problems in the control group without graft infection was 17.6%. Our series compares favorably with these results. In our aortoiliac bypass group, no patient developed graft infection, although three patients presented superficial wound infections. This finding suggests that there is still a risk for graft infection and that the use of the silver graft may also be useful for aortoiliac bypass.

Analysis of our data also showed that infection occurred significantly more often in diabetic patients and in patients who had undergone previous revascularization procedures. Again, this finding is consistent with the literature.<sup>33</sup>

Up until now, the main infection prevention techniques at the disposal of the vascular surgeon have been prophylactic antibiotics, strict antiseptic principles, and sound surgical technique. By working in synergy with these techniques, an off-the-shelf vascular graft with an antimicrobial protection that does not increase antibiotic resistance<sup>34-36</sup> could improve protection against infection with no additional risk.

As stated in the introduction, it is practically impossible to quantify the impact of this strategy on graft infection

rates in a clinical setting because of the difficulty of generating sufficient statistical power.<sup>1-4</sup> With the hypothesis of achieving a 50% decrease in graft infection between a control and silver graft group (from 1.4% to 0.7%), such a study would require 3000 patients in each group. This problem explains the disappointing results of three randomized trials of antibiotic-bonded vascular grafts.<sup>37-41</sup> Because of small size, all studies have been low powered with a resulting potential type II statistical error. It should be emphasized, however, that the problem of statistical power is equally applicable to some of the most accepted and widely practiced antiseptic techniques used in the operating room. Although the efficacy of these techniques has not been demonstrated by randomized clinical study, no one would reasonably question their benefit.

This multicenter trial is subject to the same limitations. It was neither randomized nor comparative, because such approaches are futile owing to the statistical requirements. Our purpose was not to prove the efficacy of the silver graft but to evaluate complications, patency, and rates of infection, and provide further data concerning graft infections to the medical community.

Data from various other sources have shown that the silver-coated graft can also be useful for in situ replacement of infected grafts.<sup>42-44</sup> Batt et al<sup>44</sup> addressed this issue using silver-coated polyester grafts for in situ replacement in a short series of 27 consecutive patients. Preliminary results were good, but it was difficult to draw a definite conclusion because late infections caused by organisms with low virulence developed in most of the patients. Larger series will be necessary to compare the efficacy of the silver-coated polyester grafts and other available options in an infected field.

## CONCLUSIONS

Together with data being generated in vascular graft registries, our findings improve our understanding of prosthetic infection and help to assess the contribution of the silver graft to the prevention of prosthetic infection. Our results indicate that this novel concept achieves excellent patency with a low rate of graft infection despite a high incidence of nosocomial infection. This suggests that increased antimicrobial protection in the early post-operative phase could provide long-term benefits.

## INTERGARD SILVER STUDY GROUP MEMBERS

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